Antibody-based Diagnostics

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### 2017.02.27 Translation Medicine Symposium

# What Would We Do Without Immunoassays?





#### Immunocytochemistry



Western Blot



Immunohistochemistry

# **Basic Principles of Immunoassays**



Must wash to remove unbound, active signal

# **Basic Principles of Immunoassays**



Un-removed, active signal gives high background

# Target Engaged Complementation (TEC) Binding activates reporter signal



lgG

Fab

Binding to antigen enables fragments to form active protein

# Basic Principles of "TEC"





Binding activates signal; no washing required.

# Single-step detection of soluble antigen (HER2)



Quantified HER2 levels < 1 ng/mL

Current HER2 assay has a cut-off of 15 ng/mL as criteria (Herceptest ®)

### Defining TEC assay value and finding people who care...Round 1



### Defining TEC assay value and finding people who care...Round 2



# Get smart people to tell you what the want/need

Loss-of Simul ? Better Binders 1 assaux Enzyme Activity AGENSIS Assay - looking Astellas FDA requires CDX (now ELISA) × Special Chem 20 58:0 \* g + new binder Trials QC for post translatin Mods × JFD× - antibiotics. \* Pan Basteria. PEGTS ARUP Immunolgey (Better Test) has cell line AutoImmune \* Pan Fungal for Bind Ab. " Pan Yeast RIAS - Accepty choline Receptor Block Bind Modulitin Ab 4-Tarset Automated Core hormones N-type VGCC Ab Part infusion Spike vs Biologic drug IBD Funded Chemistry Analyzer (065) Small Openchanne for Dev interference in EP tets? Ganglionic Actglcholine R Tricken Rapid check? or go to M.Sultimotely stler2 \$25/assay estridiole Immunogeneaty against biologics Triponine Conjugatin 70-20% yield anti-TNF drug levels. IFX measurement A Neutralizing Abs to ] mg scale possible PTH GY Remicade biosimilars PEGFab Fugen Mfg) Embrel

Actual white-board from strategy session with ARUP

### Application Identification

#### Assay Components



- HCI
- ARUP
- Various Research Labs

- Sources for Antibodies
  - Data Base
  - Commercial
  - In House Development

- Define "Improvement"
  - Faster
  - Cheaper
  - More Sensitive
  - Unmet need

### Streamlined TEC assay value proposition



### Streamlined TEC assay value proposition



# Lessons learned

- Good academic ideas might not be good commercial ideas
- Get to the clinic and identify the nail, then work on your hammer
- Disclose early way before you think you should



#### **ARUP Collaborators ARUP**

- Noriko Kusukawa, Ph.D. VP New Tech •
- Julio Delgado, M.D., M.S. CMO •

#### TVC

Leena Bhoite, Ph.D. – Tech Manager •

#### Research Assistant Professor/Post Docs

- Andy Dixon, Ph.D. •
- Brett "Bump" Baumgartner, Ph.D. (former) •
- Hsiao-nung Chen, Ph.D. 0

#### **Graduate Students**

- Jessica McCombs UNCF/Merck Fellow 0
- Sun Jin Kim •
- Keith Arlotta •
- Chad Adamovich (Pharm.D.) •

#### GPEN (6 month exchange)

- Sylvia Krippner •
- Bjorn ter Mors •











